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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,810	11/03/2003	Tsuneo Hattori	1828.001US2	4457

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,810	HATTORI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11,15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11,15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 03/16/06 in response to the non-final Office Action mailed 12/14/05. With this, Applicants have amended the specification and claims.

Status of Claims

2) Claims 12-14 and 16 have been canceled via the amendment filed 03/16/06.

Claims 9-11, 15 and 17 have been amended via the amendment filed 03/16/06.

Claims 9-11, 15 and 17 are pending and are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Moot

5) The objection to claims 12-14 and 16 made in paragraph 11 of the Office Action mailed 12/14/05 is moot in light of Applicants' cancellation of the claims.

Objection(s) Withdrawn

6) The objection to the specification made in paragraph 6 of the Office Action mailed 12/14/05 is withdrawn in light of Applicants' amendment to the specification.

7) The objection to claims 10 and 11 made in paragraph11 of the Office Action mailed 12/14/05 is withdrawn in light of Applicants' amendment to the claims.

Objection(s) Maintained

8) The objection to claim 15 made in paragraph 11 of the Office Action mailed 12/14/05 is maintained for reasons set forth therein and herebelow.

Rejection(s) Moot

9) The rejection of claims 12-14 and 16 made in paragraph 8(b) of the Office Action mailed 12/14/05 is moot in light of Applicants' cancellation of the claims.

10) The rejection of claims 12-14 and 16 made in paragraph 8(g) of the Office Action mailed 12/14/05 is moot in light of Applicants' cancellation of the claims.

11) The rejection of claims 11-14 and 16 made in paragraph 10 of the Office Action mailed 12/14/05 under 35 U.S.C § 102(b) as being anticipated by Suetsuna *et al.* (*Shokuniku ni kansuru Josei Kenkyu Chosa Seika Hokokusho, i.e., Report of the Promotional Research Investigation Results of Edible Means* 10 (1991): 328-334, 1992 - English translated Document of Accession number 930121753 JICST-EPlus – Applicants' IDS) is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

12) The rejection of claim 9 made in paragraph 8(a) of the Office Action mailed 12/14/05 is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claims 10, 15 and 17 made in paragraph 8(b) of the Office Action mailed 12/14/05 is withdrawn in light of Applicants' amendment to the claims.

14) The rejection of claims 9 and 10 made in paragraph 8(c) of the Office Action mailed 12/14/05 is withdrawn in light of Applicants' amendment to the claims.

15) The rejection of claim 11 made in paragraph 8(d) of the Office Action mailed 12/14/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

16) The rejection of claim 17 made in paragraph 8(e) of the Office Action mailed 12/14/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 15 made in paragraph 8(f) of the Office Action mailed 12/14/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claims 10 and 11 made in paragraph 8(g) of the Office Action mailed

12/14/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

19) The rejection of claims 9, 10, 15 and 17 made in paragraph 10 of the Office Action mailed 12/14/05 under 35 U.S.C § 102(b) as being anticipated by Suetsuna *et al.* (*Shokuniku ni kansuru Josei Kenkyu Chosa Seika Hokokusho, i.e., Report of the Promotional Research Investigation Results of Edible Means* 10 (1991): 328-334, 1992 - English translated Document of Accession number 930121753 JICST-EPlus – Applicants' IDS) is withdrawn. A modified rejection is set forth below to address the claims, as amended currently.

Rejection(s) Maintained

20) The rejection of claim 15 made in paragraph 8(g) of the Office Action mailed 12/14/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

Response to Applicants' Arguments on Suetsuna *et al.*

21) Applicants contend that the point of the Suetsuna's studies is to compare the effects of the peptides derived by enzymatic digest of porcine plasma and casein on certain immunological parameters, as compared with porcine plasma and casein. Applicants state that they agree with the Office's characterization of the reference as set forth on page 5, line 12, but disagree with the Office's characterization of the reference as it relates to the effect of the reference substance porcine plasma. Applicants submit that while porcine-plasma-derived peptide showed improved parameters as compared to porcine plasma, porcine plasma did not increase any immune function, and usually resulted in the poorest results. Applicants specifically point to section 3.4 of Suetsuna *et al.* and acknowledge that this section disclosed that "a significantly high NK activity was observed particularly in the PP diet group than in the P diet group (Figure 4)". Applicants submit that Figure 4 of Suetsuna *et al.* shows that the porcine plasma P group exhibited the lowest NK activity, which was not elevated over any standard. Applicants further state that: (a) Page 8 discloses that 'the tendency for a significantly higher [NK] activity was observed particularly in the PP diet group than in the P diet group'; (b) Figure 5 shows that the phagocytosis of AMØ was lowest in the case of the porcine plasma diet, of all the diets tested; and (c) Pages 8 and 10 disclose that the AMØ phagocytosis was high in the peptide

(CP, PP) diet groups than in the protein (C, P) diet groups, and that a significant difference was observed. Applicants conclude that: (a) Suetsuna does not disclose or suggest a method of increasing disease resistance in animals or humans by administering an immunostimulating amount of porcine plasma, alone or with crustaceae or crustaceae shells; (b) The motivation of Suetsuna's work was to study peptidyl extracts or subunits of biological materials, but not to study animal plasma as a dietary supplement; and (c) One of skill in the art in possession of Suetsuna *et al.* would be strongly motivated to digest casein or porcine plasma with pepsin to yield a peptidyl fraction that could then be used to improve the immune function of animals over that observed in animals fed a plasma or casein diet.

Applicants' arguments have been carefully considered, but are not persuasive. It must be noted that the instant claims do not require that the NK activity or the AMØ phagocytic activity of the administered swine plasma be comparatively higher than that of the peptides derived from the swine plasma. Instead, the instant claims only require that the administration of an immunostimulating effective amount of swine plasma to an animal or human increase the disease resistance in said animal or human. Suetsuna's method does exactly that and therefore anticipates the instantly claimed method. See the modified art rejection below. By stating that the NK activity and the phagocytic activity observed was higher in the PP diet group than in the 'P diet group', Applicants are in fact acknowledging the NK activity and the phagocytic activity observed with the 'P diet group' was not zero, but was indeed at a measurable level. With regard to Applicants' remarks on motivation, since Suetsuna *et al.* was applied under 35 U.S.C § 102, motivation is not a factor.

New Rejection(s) Based on Applicants' Amendment

The new rejection(s) set forth below are necessitated by Applicants' amendments to the claims.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

22) Claim 15 is rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 15, as amended currently, includes the new limitation: 'The method according to claim 10 further comprising administering fine-powdered Crustaceae, or crust of Crustaceae in a dose between 100-3000mg/kg'. Applicants point to paragraph 1 on page 7 and the working examples on pages 20-21 of the specification and state that these parts of the specification provide the descriptive support for the amendments to claim 15. However, neither the first paragraph on page 7 of the specification, nor the working examples describe a method of increasing disease resistance in an animal or human comprising the first step of administering an effective immunostimulating amount of swine plasma and a second step of further administering fine-powdered *Crustaceae* or crust of *Crustaceae*, as recited currently. Furthermore, lines 10-12 of page 7 describe the dose to be '100-3000 mg .... per 1kg body weight' of the animal or human, as opposed to the broadly recited '100-3000mg/kg', which encompass 100-3000 mg per kg of the feed. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to specific pages and lines providing the descriptive support in the specification as originally filed, for the new limitations, or remove the new matter from the claim(s).

23) Claims 10 and 11 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 10 and 11, as amended currently, include the new limitations: '100-3000 mg/kg' and '200-1200 mg/kg' respectively. Applicants state that amendments to claims 10 and 11 are specifically supported at first paragraph of page 7 of the specification. However, this part of the specification describes the dose to be '100-3000 mg .... per 1kg body weight' of the animal or human, as opposed to the broadly recited '100-3000mg/kg' and '200-1200 mg/kg', which encompass 100-3000 or 200-1200 mg per kg of the feed. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212

(CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to specific pages and lines providing the descriptive support in the specification as originally filed, for the new limitations, or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

24) Claims 9-11, 15 and 17 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 9 is vague, indefinite, confusing and/or inconsistent in scope with regard to the limitations: 'animals and humans' (see line 1) and 'the animal or human' (see line 3). For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the above-identified limitation in line 1 of claim 9 with --an animal or a human--.

(b) Claims 10, 11, 15 and 17, which depend directly or indirectly from claim 9, are also rejected as being indefinite because of the vagueness or indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

25) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> **(e)** the invention was described in-
> **(2)** a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

26) Claims 9-11 and 17 are rejected under 35 U.S.C § 102(b) as being anticipated by Suetsuna *et al.* (*Shokuniku ni kansuru Josei Kenkyu Chosa Seika Hokokusho, i.e., Report of the Promotional Research Investigation Results of Edible Means* 10 (1991): 328-334, 1992 - English translated Document of Accession number 930121753 JICST-EPlus – already of record).

The page number referred to below represent the page number of the translated document.

It is noted that the phagocytic ability (or index) to foreign matter is used as a measure of natural immune function. See Example 1 and first full paragraph on page 13 of the specification.

Suetsuna *et al.* taught a method of significantly increasing the natural killer cell activity of splenocytes and increasing the phagocytosis of opsonized sheep RBCs by alveolar macrophages (i.e., increasing disease resistance) by administering to rats, via food, porcine plasma protein. See abstract; first full paragraph on page 1; and section 2.2. The amount of porcine plasma protein (P) contained in the rat cornstarch diet was 15% (see section 2.2 and Table 1). The administration of porcine plasma protein to rats increased the weight of rat thymus and spleen, the organs responsible for natural immunity (see section 3.3, page 8, and last paragraph on page 9). Rats administered with porcine plasma showed high natural killer activity (see section 3.4, Figure 4, and page 8) and increased phagocytosis of opsonized sheep RBCs (see section 3.6, Figure 5, page 8, and first paragraph on page 10). Furthermore, Suetsuna *et al.* taught the close relationship between the immunity or protection mechanism of the host (i.e., disease resistance) and the nutrition state of the host's living body. Suetsuna *et al.* further taught of the existence of frequent susceptibility to infections and generation and promotion in the progression of cancers in nutritionally abnormal states (see section 4). Suetsuna's rat diet product qualifies as a food product, animal feed, or a pharmaceutical. Although Suetsuna *et al.* do not expressly include the one-day dose range limitation of '100-3000 mg/kg' or '200-1200' mg/kg', since the prior art method brought about the same effect of increasing disease resistance, i.e., fortifying bio-defense mechanisms including phagocytic activity towards foreign matter, such as, sheep RBCs, and the enhanced NK cell and macrophage activity, the prior art method is viewed as necessarily including the administration of a dose of '100-3000 mg/kg' or '200-1200' mg/kg' of porcine plasma protein to the rats included in the study. That the porcine plasma used in Suetsuna's method showed NK cell activity of splenocytes and phagocytic activity towards opsonized sheep red blood cells, and an action on alveolar macrophages, indicates the presence of immune activating (i.e., immunostimulating) factors in porcine plasma, and suggests that the immune-activating porcine plasma product administered to rats in Suetsuna's method necessarily contained '100-3000 mg/kg' or '200-1200' mg/kg' of porcine plasma protein. Since the Office does not have the facilities for examining and comparing Applicants' swine plasma dose range with the porcine plasma dose administered to rats in Suetsuna's method, the burden is on the

Applicants to show a novel or an unobvious difference between the instantly claimed method and the prior art method. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzerald et al.*, 05 USPQ 594.

Claims 9-11 and 17 are anticipated by Suetsuna *et al.*

27) Claims 9-11 and 17 are rejected under 35 U.S.C § 102(e)(2) as being anticipated by Langrehr (US 6,156,333, filed 07/10/1995 – Applicants' IDS) as evidenced by Stahly *et al.* (*ISU Swine Research Report*, pages 3-5, 1994).

Langrehr disclosed a method of feeding (i.e., administering) preruminant calves with a feed containing comprising 10-50% or 25-26% by weight (i.e., effective immunostimulating amount) of porcine plasma. The porcine plasma-containing feed enhances and improves the nutritional diet of the calves and helps to protect calves from pathogenic microorganisms and other harmful diseases (see paragraph bridging columns 4 and 5 and columns 5 and 6; second paragraph in column 11; Example 1; and claims 1 and 2). The plasma stimulates the immune system of the calf (see line 54 in column 5). That the porcine plasma used in Langrehr's method induced an immunostimulating effect is inherent from the disclosure of Langrehr in light of what is well known in the art. For instance, in 1994, Stahly *et al.* taught the immunomodulating properties or impact of dietary porcine plasma proteins on postweaning animals by modulating the animals' susceptibility to environmental foreign antigens by activating their body immune defenses (see page 3). Therefore, Langrehr's method is expected to serve as a method of increasing disease resistance in the preruminant calves fed with porcine plasma-containing feed by stimulating the immune system of the calves, by protecting the calves from pathogenic microorganisms and other harmful diseases and by modulating the animals' susceptibility to environmental foreign antigens by activating their body immune defenses. Although Langrehr's disclosure does not expressly include the dose range limitation of '100-3000 mg/kg' or '200-1200' mg/kg', since the prior art method provides the effect of immunostimulating, i.e., increasing disease resistance, the prior art method is viewed as necessarily including the administration of a one-day dose of '100-3000 mg/kg' or '200-1200' mg/kg' of porcine plasma protein to the calves included in the study. Since the Office does not have the facilities for examining and comparing Applicants' swine plasma dose range with the porcine plasma dose administered to calves in Langrehr's method, the burden is on the Applicants to show a novel or

an unobvious difference between the instantly claimed method and the prior art method. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzerald et al.*, 05 USPQ 594.

Claims 9-11 and 17 are anticipated by Langrehr. Stahly *et al.* is **not** used as a secondary reference in combination with Langrehr, but rather is used to show that every element of the claimed subject matter is disclosed by Langrehr with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Remarks

28) Claims 9-11, 15 and 17 stand rejected.

29) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The central Fax number for submission of amendments, responses or papers is (571) 272-8300, which receives transmissions 24 hours a day and 7 days a week.

31) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

32) Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

April, 2006

S. DEVI, PH.D.
PRIMARY EXAMINER